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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,398	08/23/2006	Petra Gisela Rigassi-Dietrich	33688-US-PCT	8737

1095 7590 05/17/2011

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 101/2
EAST HANOVER, NJ 07936-1080

EXAMINER	
VU, JAKE MINH	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
05/17/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,398	RIGASSI-DIETRICH ET AL.	
	Examiner	Art Unit	
	JAKE VU	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-39* is/are pending in the application.

4a) Of the above claim(s) *15-20,23,30 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,22,24-29 and 32-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Request for Continued Examination and Amendment filed on 11/02/2010.

- Claims 32 and 32 have been amended.
- Claims 15-39 are pending in the instant application.
- Claims 15-20, 23, 30-31 are withdrawn from consideration.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/02/2010 has been entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-22, 24-29, 32-39 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over copending Application No. 11/153,728; 11/119,273; and 11/219,273 **are maintained** for reasons of record in the previous office action filed on 03/09/2009.

Note, it is acknowledged that Applicant requests that the Office hold all provisional double patenting rejections in abeyance pending claim allowance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Upon closer examination, claim 32 recites the limitation "about 332 mg" in claim 29. There is insufficient antecedent basis for this limitation in the claim, because the amount is outside of the range of claim 29, which recites from "about 75 to 300 mg". The Examiner assumes claim 32 should have been dependent on claim 28.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-22, 24-29, 32-39 are rejected under 35 U.S.C. 102(a,e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WEBB (US 2003/0114389).

Applicant's claims are directed to a composition comprising of: about 332 mg of aliskiren in the hemi-fumarate salt form; fillers, such as microcrystalline; disintegrant; lubricant; glidant; binder; and a film-coating. Additional limitation includes: 46-60% of aliskiren; is not produced by wet granulation using water and/or aqueous binder solution, such as organic solvents.

WEBB teaches a composition comprised of: 100mg (see [0077]) of formula I (see [0001]), which is aliskiren, in the hemi-fumarate salt form (see [0077]); a filler, such as microcrystalline (see [0079]); a disintegrant, such as sodium carboxymethyl starch (see [0077]); a lubricant, such as magnesium stearate (see [0077]); a glidant, such as colloidal silicic acid (see [0077]); a binder, such as corn starch (see [0077]); and a film-

coating (see [0076]). Additional disclosure includes: about 1-80% of the active compound (see [0067]); 45.5% of aliskiren (see example in [0077]); the active compound could be made in ranges of 10-500mg (see [0072]); the composition could be made by other methods than wet granulation, such as convention mixing, coating, and lyophilizing processes (see [0067]).

Note, with regard to claim 39, this claim recites a composition, and the intended use recited in the preamble would reasonably appear not to be a claim limitation. "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim…If, however, the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." Pitney Bowes, Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). Thus, the intended use of treating hypertension in the composition claims is met by the prior art, because the prior art compositions would be at least capable of performing said use.

Note, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-

by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, the method of producing the composition by not using wet granulation with excipients using water and/or an aqueous binder solution has no patentable limitation, since the prior art's product has the same ingredients as claimed by Applicant.

Response to Arguments

Applicant argues that the claimed invention is not anticipated by the '389 application. Claim 21 recites an oral dosage form not obtainable by wet granulation with excipients using water. The '389 application requires the use of water, as disclosed in 78 and 80. Therefore, the '389 application does not disclose all limitations of the pending claims.

The Examiner finds this argument unpersuasive, because as discussed above, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, the method of producing the composition by not using wet granulation with excipients using water and/or an aqueous binder solution has no patentable limitation, since the prior

art's product has the same ingredients as claimed by Applicant and the prior art's final product does not contain water, since it is a tablet (see WEBB at [0076]).

Applicant argues that the '389 application does not render the claimed invention obvious. A prima facie case of obviousness must establish that there is a reasonable expectation of success at arriving at Applicant's claimed subject matter, using the cited art as a starting point. However, the '389 application does not provide a reasonable expectation of success at arriving at a high-dose aliskiren tablet. Aliskiren is very difficult to formulate and, prior to the claimed invention, it had not been possible to make oral forms in the form of tablets in a reliable and robust way. The flow properties, bulk density, compression behavior and elastic properties pose a formidable hurdle to achieving the high drug load necessary to achieve a reasonable tablet size. Present application at paragraph 6-7. Furthermore, the highly hygroscopic nature of aliskiren makes it inherently unstable, making standard tablet manufacturing processes extremely difficult to achieve. Present application at paragraph 8.

The Examiner finds this argument unpersuasive, because WEBB teaches that the active compound could be made in ranges up to 500mg (see [0072]); thus, one of ordinary skill in the art would have a reasonable expectation of success.

Applicant argues that the present application discloses, for the first time, the unexpected finding that an aqueous granulation process leads to a change in polymorphism which negatively affects the stability of the drug product but, in contrast, an organic granulation process produces a superior oral dosage form. The organic granulation process yields a drug substance with improved characteristics such that it

can be formulated into stable aliskiren tablets with a high drug load, sufficient hardness and resistance to friability. The '389 application does not provide a reasonable expectation of success in achieving the claimed invention. It merely states that the disclosed pharmaceutical preparations can be prepared in a manner that is known per se. The '389 application at paragraph 67. It provides no disclosure of organic granulation and no data to support a tablet produced in such a manner. At best, the '389 application provides a wish, and is not sufficient to be considered enabling art. It does not provide any expectation that a high-load aliskiren tablet can be produced by organic granulation.

The Examiner finds this argument unpersuasive for numerous reasons, such as (1) Applicant's independent claim 21 does not recite using an organic granulation process; (2) Applicant's specification states granulation liquid can include water with the ethanol (see specification at [0089]); thus, the organic granulation would include water; and (3) Applicant's specification does not provide any real data showing the unexpected better stability of the drug when using organic solvents versus water.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618